K121772

MAR 2 1 2013

510(k) Summary of Safety and Effectiveness

3D Interventional tools software medical device

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR § 807.92.

Date prepared: March, 1 2013

Identification of manufacturer

Company:	Philips Medical Systems Nederland B.V.
Address:	Veenpluis 4-6, 5684-PC, Best, The Netherlands
Registration number:	3003768277

Identification of U.S. designated agent

Company:	Philips Medical Systems
Address:	22100 Bothell Everett Highway Bothell, WA 98021-8431, U.S.A.
Registration number:	1217116

Identification of official correspondent

Name:	Liselotte Kornmann, PhD Regulatory Affairs Manager
Address:	Philips Medical Systems Nederland B.V. Veenpluis 4-6, 5684-PC, Best, The Netherlands
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Device identification

Trade name:	Allura 3D-RA, 3D Roadmap, MR-CT Roadmap
Device name:	Allura 3D-RA. Rel. 6, 3D Roadmap Rel. 1, MR-CT Roadmap Rel. 1
Regulation description:	Image-intensified fluoroscopic x-ray system
Regulation number:	21CFR 892.1650
Class:	II
Product code:	OWB, JAK, LLZ

Legally marketed devices

Trade names:	Allura 3D-RA Rel. 4.2
Manufacturer:	Philips Medical Systems
510(k) numbers:	K040254 - Feb 19, 2004
Trade names:	Innova Vision Applications
Manufacturer:	GE Medical Systems
510(k) numbers:	K092639 - Dec 2, 2009

Device description

The device description of the **3D Interventional Tools** software medical devices that are subject of this 510(k) submission are as follows:

Allura 3D-RA Rel. 6 software medical device (Allura 3D-RA Rel. 6)

The **Allura 3D-RA Rel. 6** is a software product (Interventional Tool) intended to provide high-speed and high resolution 3D visualization of vessels and bones anatomy. Allura 3D-RA is intended to be used in combination with an Allura X-ray system.

The **Allura 3D-RA Rel. 6** generates a 3D reconstruction from 2D X-ray images to visualize vascular anatomy, and helps to identify vascular pathologies from a single contrast-enhanced rotational angiogram. It can be used during any angiography procedure and can cover any anatomical area including cerebral, abdominal, and peripheral. It also allows for 3D visualization of the spine.

3D Roadmap Rel. 1 software medical device (3D Roadmap Rel. 1)

The **3D Roadmap Rel. 1** is a software product intended (Interventional Tool) to assist the physician during complex interventions by providing live 3D image guidance for navigating endovascular devices through vascular structures anywhere in the body. 3D Roadmap is intended to be used in combination with an Allura X-ray system.

The **3D Roadmap Rel. 1** overlays live 2D fluoroscopic images on a 3D reconstruction of the vessel tree processed by **Allura 3D-RA Rel. 6** and therefore, assist the physician in catheter maneuvering. It can be used during any endovascular intervention and can cover any anatomy, including cerebral, abdominal, and peripheral vasculature.

MR-CT Roadmap Rel. 1 software medical device (MR-CT Roadmap Rel. 1)

The **MR-CT Roadmap Rel.1** is a software product intended to provide live 3D image guidance for navigating endovascular devices through vascular structures anywhere in the body, reusing segmented MRA or CTA data that has been acquired previously. The **MR-CT Roadmap Rel.1** is intended to be used in combination with an Allura X-ray system.

The **MR-CT Roadmap Rel.1** overlays live 2D fluoroscopic images on a previously acquired MRA or CTA volume, which is registered by the **Allura 3D-RA Rel. 6** with the X-ray system using a rotational scan and therefore, assist the physician in catheter maneuvering. It can be used during any endovascular intervention and can cover any anatomy, including for example cerebral, abdominal, and peripheral vasculature.

Indications for Use:

The indications for use of the **3D Interventional Tools** software medical devices are as follows:

Allura 3D-RA Rel. 6

- The **Allura 3D-RA Rel. 6** is intended to assist physicians in analyzing two dimensional X-ray images by creating three dimensional views from sets of two dimensional images created during rotational angiographic runs.
- The **Allura 3D-RA Rel. 6** is intended to assist in the diagnosis and treatment of endovascular diseases, for example, stenosis, aneurysms, and arteriovenous malformations.
- The **Allura 3D-RA Rel. 6** also supports measurement of lesion dimensions and anatomical distances.

3D Roadmap Rel.1

- **3D Roadmap Rel. 1** is an extension of Allura 3D-RA, which provides image guidance by superimposing live fluoroscopic images on a 3D reconstruction of the vessel anatomy to assist in catheter maneuvering.
- The **Allura 3D-RA Rel. 6** is intended to assist in the diagnosis and treatment of endovascular diseases, for example, stenosis, aneurysms, and arteriovenous malformations.

MR-CT Roadmap Rel.1

- **MR-CT Roadmap Rel. 1** is an extension of Allura 3D-RA, which provides image guidance by superimposing live fluoroscopic images on a 3D reconstruction of the vessel anatomy to assist in catheter maneuvering.
- The **Allura 3D-RA Rel. 6** is intended to assist in the diagnosis and treatment of endovascular diseases, for example, stenosis, aneurysms, and arteriovenous malformations.

Technological characteristics

The technological characteristics of the **3D Interventional Tools** software medical devices are as follows:

The **Allura 3D-RA Rel. 6, 3D Roadmap Rel. 1 and MR-CT Roadmap Rel. 1** software medical device applications are extensions of the currently marketed and predicate Allura 3D-RA rel 4.2 with new functionality that are built re-using the same technology. They are provided on the hosting software functionality platform of the currently marketed and predicate Allura 3D-RA Rel 4.2. Please note that upon receiving 510(k) clearance (K121296) from FDA for the independent hosting software functionality platform, **Interventional Workspot**, which is currently pending with FDA, the **Allura 3D-RA Rel. 6, 3D Roadmap Rel. 1 and MR-CT Roadmap Rel. 1,** will be provided as separate software medical devices.

Summary of testing

Verification and validation tests were performed with regards to Intended Use, Claims, Requirement specifications and Risk management requirements. The test results demonstrate that the **Allura 3D-RA Rel. 6, 3D Roadmap Rel. 1 and MR-CT Roadmap Rel. 1** software medical devices comply with all the requirements, including international recognized standards as detailed in this premarket submission and met the acceptance criteria.

This premarket submission included an in-house validation study to assess the performance of the aneurysm tool in segmentation of the aneurysm. In this retrospective study performed on 3DRA clinical datasets with aneurysms, the performance of the tool was validated by three experts; one of the experts was an interventional neuro radiologist. The aneurysm tool can be used successfully for aneurysms between 2 and 22 mm that are not located on crossing vessels. According to the validation study, the average success rate of segmentation is 73% with a 95% confidence interval of [60%, 100%].

Conclusion:

The **3D Interventional Tools software medical devices** are substantially equivalent to the currently marketed and predicate devices, based on the similar design functionality, indications for use and software requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 21, 2013

Philips Medical Systems Nederland B.V.
% Liselotte Kornmann, Ph.D.
Regulatory Affairs Manager
Veenpluis 4-6
5684-PC, BEST
THE NETHERLANDS

Re: K121772
Trade/Device Name: Allura 3D-RA Rel. 6, 3D Roadmap Rel. 1, MR-CT Roadmap Rel. 1
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAK, LLZ
Dated: February 28, 2013
Received: March 05, 2013

Dear Dr. Kornmann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

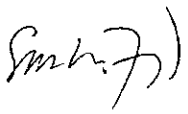
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121772

Device Name: 3D Roadmap Rel. 1

Indications For Use:

The **3D Roadmap Rel. 1** is an extension of Allura 3D-RA, which provides image guidance by superimposing live fluoroscopic images on a 3D reconstruction of the vessel anatomy to assist in catheter maneuvering.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Division of Radiological Health
510(k): K121772

Indications for Use

510(k) Number (if known): K121772

Device Name: Allura 3D-RA Rel. 6

Indications For Use:

The **Allura 3D-RA Rel. 6** is intended to assist physicians in analyzing two dimensional X-ray images by creating three dimensional views from sets of two dimensional images created during rotational angiographic runs.

The **Allura 3D-RA Rel. 6** is intended to assist in the diagnosis and treatment of endovascular diseases, for example, stenosis, aneurysms, and arteriovenous malformations.

The **Allura 3D-RA Rel.6** also supports measurement of lesion dimensions and anatomical distances.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Division of Radiological Health

510(k): K121772

Indications for Use

510(k) Number (if known): K121772

Device Name: MR-CT Roadmap Rel. 1

Indications For Use:

The **MR-CT Roadmap Rel. 1** is an extension of Allura 3D-RA, which provides image guidance by superimposing live fluoroscopic images on a 3D reconstruction of the vessel anatomy to assist in catheter maneuvering.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Division of Radiological Health

510(k): K121772